UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, DC 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/439,095	05/11/95	MATSUI T	40399/119

18M2/0225

FOLEY & LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON DC 20007-5109

EXAMINER	
MARSCHEL, A	
ART UNIT	**PAPER NUMBER**
1809	

DATE MAILED: 02/25/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

☆U.S.GOVERNMENT PRINTING OFFICE 1995-319-826

Office Action Summary

Application No.	Applicant(s)
08/439,095	Matsui et al.
Examiner	**Group Art Unit**
Ardin Marschel	1809

☒ Responsive to communication(s) filed on 11-25-96 and 12-5-95

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 2-16, 18, 19, and 22-29 is/are pending in the application.

Of the above, claim(s) 8-15 is/are withdrawn from consideration.

☒ Claim(s) 22 and 26-29 is/are allowed.

☒ Claim(s) 2-7, 16, 18, 19, 23, and 24-25 is/are rejected.

☒ Claim(s) _____ is/are objected to.

☒ Claims 2-16, 18, 19, and 22-29 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, ~~Paper No(s).~~ 3 sheets

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1809.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Reconsideration of the disclosure as filed has revealed that the cDNA for human αPDGF receptors has been disclosed with sequence information to define the specific receptor sequence and protein such as given in Figure 3. It is noted that Figure 3 shows a reasonably lengthy sequence. The concern is that there has been no illustration as to what sequence variations still result in a human αPDGF receptor sequence. There is no guidance as to what portions of the Figure 3 sequence is critical versus segments that may be altered without causing functional changes in the protein. It is also noted that the specification as filed does not define what criteria should be used to test whether an altered sequence is still human αPDGF receptor sequence. Is it governed by percent sequence homology? Is it defined by functional criteria such as PDGF isoform binding? This complete lack of guidance regarding what changes in sequence are permissible or suggested results in an invitation to experiment beyond the sequences in Figure 3. Therefore claims such as 23

and 24 lack enablement beyond human αPDGF receptor sequence as given in Figure 3. In summary, claims 4-6, 23, and 24 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to sequence as shown in Figure 3. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claims 2, 3, 18, and 19 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The above listed claims either cite the phrase "according to" or "defined by". The metes and bounds of these phrases are vague and indefinite as to whether the Figure 3 sequence is exactly present in claim embodiments or whether the Figure 3 sequence is a guide with some percentage variance permissible. Clarification is requested by clearer claim wording.

Claim 16 is rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 16 broadens rather than further limits the scope of claim 3 from which it depends because claim 16 is only limited to at least 5 consecutive amino acids whereas claim 3 is far more limited to all of the amino acids shown in Figure 3.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24 is rejected under 35 U.S.C. § 102(b) as being anticipated by product 1033 of the New England Biolabs 1986/87 Catalog.

Product 1033: CCCCGGGG (NEB Catalog page 61, line 6)
||||||
Instant Figure 3: GGGGCCAC at position 2091

No such 7 out of 8 base match has been found in the βPDGF receptor sequence. Product 33 thus reads on instant claim 24 in that the stringency of hybridization between product 1033 and the αPDGF receptor nucleic acid is high relative to that for βPDGF receptor sequence.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claim 7 is rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over either Hart et al. or Betsholtz et al., taken in view of Raines et al. and further in view of Hart (P/N 5,094,941).

The PDGF receptors detected and isolated by Hart et al. are disclosed to include an approximately 130 kDa form in the abstract and also shown as measured as having a molecular weight of 128 kDa in Figure 5 on page 10783. The 128 kDa band in Figure 5 is a disclosure of an isolated form of said receptor shown in a Western blot. It binds PDGF as expected for a PDGF receptor. Similarly, Betsholtz et al. disclose a 115 kDa protein in Figure 6 on page 451 which is discussed on page 450, first column, last paragraph, as a protein expressed as a result of PDGF stimulation of human fibroblast cells which also appears to meet the basic requirement of alpha PDGF receptor. The receptors of either Hart et al. or Betsholtz et al. therefore meet the basic characteristics as instantly disclosed but is not characterized further such as regarding which PDGF isoforms are specifically bound by said receptor as is instantly studied and defined for the alpha form of the human PDGF receptor protein. It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art

discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph). In the instant application the receptor has the same molecular weight as the prior art receptor and binds PDGF as a PDGF receptor must. Secondly, several forms of the PDGF receptor are disclosed in Hart et al. which indicates that both the beta and alpha form at least are therein disclosed. Lastly, it is noted that the instant disclosure further characterizes the alpha receptor regarding PDGF isoform binding as well as amino acid sequence. These further characterizations appear to be merely the measurement of inherent properties of the prior art protein which meets the basic characterization also.

Hart et al. and Betsholtz et al. disclose the basic characteristics of the alpha PDGF receptor including binding PDGF. No detailed characterization of PDGF, however, is therein discussed. The preparation of PDGF is referenced to reference 30 by Raines et al. Consideration of Raines et al. revealed that reference 30 is actually a publication in the Journal of Biol. Chem. as cited on the enclosed PTO 892. Consideration of Raines et al. reveals that multiple forms of PDGF are contained in the isolated PDGF preparation. Hart (P/N 5,094,941) at column 1, line 44, through column 2, line 27) discloses this PDGF as

containing AA, AB, and BB isoforms thus including all of the forms that may be bound by the receptor of Hart et al. although not specifically characterized therein. In summary, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to isolate alpha PDGF receptor as given in either Hart et al. or Betsholtz et al. and characterize it to determine the inherent properties as instantly disclosed because the different isoforms of PDGF were known in Hart (P/N 5,094,941) which as gives the suggestion that a form of PDGF receptor binds all three isoforms. Sequencing per se of a protein is also the determination of an inherent property of a protein, even though performed by genetic engineering methods.

Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 22 and 26-29 are allowed.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 305-3014 or (703) 308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

February 18, 1997

Ardin H. Marschel

ARDIN H. MARSCHEL
PRIMARY EXAMINER
GROUP 1800